

## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/976,451	10/12/2001	Jonathan Braun	P-PM 4968

CONFIRMATION NO. 1617

## FORMALITIES LETTER



\*OC000000007072292\*

CAMPBELL & FLORES LLP  
7th Floor  
4370 La Jolla Village Drive  
San Diego, CA 92122

Date Mailed: 11/15/2001

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

01/31/2002 JADD01 00000044 09976451

## FILED UNDER 37 CFR 1.53(b)

01 FC:201	370.00 OP
02 FC:202	210.00 OP
03 FC:204	140.00 OP
04 FC:205	65.00 OP
05 FC:203	153.00 OP

## Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 740 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- Total additional claim fee(s) for this application is \$1042.
  - \$342 for 19 total claims over 20.
  - \$420 for 5 independent claims over 3.
  - \$280 for multiple dependent claim surcharge.
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is \$ 1912.**
- This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant

desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

For questions regarding compliance t these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or [patin3help@uspto.gov](mailto:patin3help@uspto.gov)

---

*A copy of this notice MUST be returned with the reply.*



Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



BEST AVAILABLE COPY

PATENT

Our Docket: P-PM 4968

UCLA Reference: 2001-114-2

COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Braun et al. )  
Serial No.: 09/976,451 )  
Filed: October 12, 2001 )  
For: METHODS OF DIAGNOSING )  
AND TREATING CROHN'S )  
DISEASE USING PSEUDOMONAS )  
ANTIGENS )

Examiner: Not yet assigned

Group Art Unit: 1645

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Missing Parts, Commissioner for Patents, Washington, D.C. 20231, on January 15, 2002.

By Andrea L. Gashler  
Andrea L. Gashler, Reg. No. 41,029

COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231  
Attention: BOX MISSING PARTS

January 15, 2002  
Date of Signature

MISSING PARTS TRANSMITTAL

Dear Sir:

In response to the Notice to File Missing Parts mailed November 15, 2001, enclosed are:

- X 1. A copy of the Notice to File Missing Parts;
- X 2. An executed Declaration for Patent Application;
- X 3. A Recordation Form Cover Sheet and an executed Assignment;
- X 4. An executed Small Entity Statement executed by Prometheus Laboratories, Inc.;
- X 5. An executed Small Entity Statement executed by The Regents of the University of California;
- X 6. An executed Power of Attorney by Assignee and Exclusion of Inventor(s) Under 37 C.F.R. 3.71;
- X 7. A Statement Under CFR 3.73(b) with copy of executed Assignment executed by The Regents of the University of California;
- X 8. Information Disclosure Statement;
- X 9. PTO Form-1449 with 93 references attached;
- X 10. Paper copy of sequence listing, pages 1 through 8;
- X 11. Statement Under 37 C.F.R. § 1.821(f) and (g);
- X 12. Sequence listing in computer readable form.

The filing fee has been calculated as shown below:

	NUMBER FILED		NUMBER EXTRA		RATE		FEE		
					SMALL ENTITY	OTHER ENTITY		SMALL ENTITY	OTHER ENTITY
TOTAL CLAIMS	37 - 20	=	17	x	\$9	\$18	=	\$153	\$
INDEPEN- DENT CLAIMS	8 - 3	=	5	x	\$42	\$84	=	\$210	\$
MULTIPLE DEPENDENT CLAIMS PRESENTED: <u>  X  </u> YES <u>      </u> NO					\$140	\$280	=	\$140	\$
					BASIC FEE			\$370	\$740
					TOTAL FEE			\$873	

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 2

BEST AVAILABLE COPY

- X 13. A check in the amount of \$978.00 to cover the filing fee of \$873.00, the surcharge fee of \$65.00, and \$40.00 for recording an Assignment for the application is enclosed.
- X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.
- X Any additional filing fees required under 37 C.F.R. 1.16.
- X Any patent application processing fees under 37 C.F.R. 1.17.
- X The Commissioner is hereby authorized to charge to Deposit Account No. 03-0370 any fees under 37 CFR 1.17 which may be required under 37 CFR 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted

Date: January 15, 2002

By: Andrea L. Gashler  
Andrea L. Gashler  
Registration No.: 41,029

CAMPBELL & FLORES LLP  
4370 La Jolla Village Drive  
7<sup>th</sup> Floor  
San Diego, California 92122  
Telephone: (858) 535-9001  
Facsimile: (858) 535-8949  
USPTO CUSTOMER NO. 23601



PATENT  
Our Docket: P-PM 4968  
UCLA Reference: 2001-114-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	
Braun et al.	)	Examiner: Not yet assigned
	)	
Serial No.: 09/976,451	)	Group Art Unit: Unknown
	)	
Filed: October 12, 2001	)	
	)	
For: METHODS OF DIAGNOSING	)	
AND TREATING CROHN'S	)	
DISEASE USING <i>PSEUDOMONAS</i>	)	
ANTIGENS	)	
	)	
<hr/>		
Commissioner for Patents		
Washington, D.C. 20231		

SMALL ENTITY STATEMENT

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons.  
§ 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 2 of 4

entities may not be more than 49%. 13 C.F.R.  
§ 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months.

"Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

**(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C), (D).

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 3 of 4

Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include an inventor him- or herself or an authorized officer of the assignee, where the assignee has at least an undivided part interest in the application or patent. § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity: If the rights in the invention held by the Party are not exclusive, each party having rights in the invention is listed below:

**Prometheus Laboratories, Inc.**

Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 4 of 4

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

Dated: December 10, 2001  
Signature: Linda S. Stevenson  
Typed Name: Linda S. Stevenson  
Title: Manager, Patent Prosecution  
Office of Technology Transfer  
1111 Franklin Street, 12 Floor  
Oakland, CA 94607-5200





PATENT

Our Docket: P-PM 4968

UCLA Reference: 2001-114-2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: )  
Braun et al. ) Examiner: Not yet assigned  
Serial No.: 09/976,451 ) Group Art Unit: Unknown  
Filed: October 12, 2001 )  
For: METHODS OF DIAGNOSING )  
AND TREATING CROHN'S )  
DISEASE USING *PSEUDOMONAS*)  
ANTIGENS )

Commissioner for Patents  
Washington, D.C. 20231

**SMALL ENTITY STATEMENT**

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons..  
§ 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 2 of 4

entities may not be more than 49%. 13 C.F.R.  
§ 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months.

"Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

### **(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C), (D).

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 3 of 4

Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include an inventor him- or herself or an authorized officer of the assignee, where the assignee has at least an undivided part interest in the application or patent. § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, each party having rights in the invention is listed below:

**The Regents of the University of California**

Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

Inventors: Braun et al.  
Serial No.: 09/976,451  
Filed: October 12, 2001  
Page 4 of 4

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

Dated:

12/12/01

Signature:

R.B. Rich

Typed Name:

RUSSELL B. RICHMOND

Title:

Vice President Research and Development

Prometheus Laboratories, Inc.  
5739 Pacific Center Boulevard  
San Diego, California 92121-4203